K063609

510(k) Summary

ırsuant to CFR 807.92, the following 510(k) Summary is provided:

(a)	**Submitter's Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726
(b)	***Manufacturer Address:***	SHL Telemedicine International, Ltd. 90 Igal Alon Street Tel Aviv Israel, 67891
	Mfg. Phone:	972-3-561-2212
	Contact Person:	Iki Alroy, CTO/Vice President of R&D
	Date:	November 30, 2006

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2.	***Device & Classification Name:***	Electrocardiograph Telephone Transmitter and Receiver (Class 2), Product Code DXH, 21 CFR 878.2920 – Tradename of device: **River-1** ***Electrocardiograph (ECG) Recorder and Transmitter***
3.	***Predicate Devices:***	King of Hearts® Express+ AF Monitor K020825 VST™ Vital Signs Recorder and Transmitter K040942 CardioCall™ Event Recorder K972649
4.	***Description:***	The River-1 is a patient activated electrocardiograph (ECG) symptomatic event recorder and transmitter. The River is a looping type ECG recording device (it records the ECG continuously). When the patient presses the ECG Record Button to record an ECG, the device stores both the recently recorded ECG and the ECG, following activation. The recorded ECG can then be transmitted to a healthcare facility or receiving center via two distinct channels: digitally via cellular network or acoustically via any phone. The River-1 is a portable programmable device which is worn on the belt of the patient. It features a simple LCD screen, key pad, and is powered by a rechargeable battery. It can accommodate up to three leads for the option of recording 1, 2, or 3 lead ECG data.
5.	***Intended Use:***	The River 1 is indicated for the evaluation of patients who experience transient symptoms such as dizziness, palpitations, syncope, or chest pain that might suggest arrhythmia. The device is intended to record cardiac activity associated with these infrequent and transient symptoms. Once the data is recorded, the patient transmits this ECG data over the telephone or cellular network to a remote central receiving station to be reviewed by a healthcare professional.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the River-1 System is substantially equivalent to its predicate devices in that it that it is a patient activated looping device which records and transmits ECG data over the telephone or cellular network. It also has the same basic intended uses as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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SHL Telemedicine International, Ltd.
c/o Mr. George J. Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
Somerset, MA 02726

Re: K063609
Trade/Device Name: River-1 Electrocardiograph (ECG) Recorder and Transmitter
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: September 4, 2007
Received: September 7, 2007

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063609

Device Name: SHL Telemedicine River-1

Indications For Use: The River-1 is indicated for the evaluation of patients who experience transient symptoms such as dizziness, palpitations, syncope, or chest pain that might suggest arrhythmia. The device is intended to record cardiac activity associated with these infrequent and transient symptoms. Once the data is recorded, the patient transmits this ECG data over the telephone or cellular network to a remote central receiving station to be reviewed by a healthcare professional.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063609